Amendment

In the Claims

1-10. (cancelled)

11. (currently amended) A formulation comprising a population of non-polymer encapsulated nanoparticles ~~comprising at least 95% nanoparticles~~ of a therapeutic, diagnostic or prophylactic agent wherein at least 95% of all of the nanoparticles have ~~having~~ a diameter of less than one micron.

12. (currently amended) The formulation of claim 11, wherein the agent is selected from the group consisting of ~~small molecule~~ drugs which are soluble in water to less than about 0.1% w/v at room temperature, proteins, lipids, polysaccharides, proteoglycans, and polynucleotides.

13. (previously presented) The formulation of claim 11, wherein the agent is soluble in water to less than about 0.1% w/v at room temperature.

14. (cancelled)

15. (previously presented) The formulation of claim 11, wherein at least 99% of the nanoparticles have a diameter of less than one micron.

16. (previously presented) The formulation of claim 11 further comprising bioadhesive enhancing agents.

17. (previously presented) The formulation of claim 11 further comprising a dispersant.

18. (previously presented) The formulation of claim 11 further comprising a polymer.

19. (previously presented) The formulation of claim 11 comprising a polymer encapsulated agent having bioadhesive agent bound thereto or dispersed therein.

20. (previously presented) The formulation of claim 16, wherein the bioadhesive agent is selected from the group consisting of bioadhesive metal compounds and bioadhesive organic molecules.

21. (previously presented) The formulation of claim 11, wherein the nanoparticles are formed by a method comprising

dissolving the bioactive agent in a solvent to form a first solution;

providing a non-solvent for the bioactive agent, wherein the non-solvent is miscible with the solvent; and

mixing the first solution with the non-solvent to form nanoparticles.

22. (currently amended) A non-polymer encapsulated nano or microparticulate formulation for oral administration of a taxane wherein the non-polymer encapsulated nanoparticles comprise taxane and the formulation has ~~providing~~ a bioavailability when administered orally of at least 5% of the bioavailability of the taxane when administered intravenously.

23. (previously presented) The formulation of claim 22 wherein the taxane is paclitaxel.

24. (previously presented) The formulation of claim 22 wherein the taxane is docetaxel.

25. (previously presented) The formulation of claim 22 wherein 90%, by volume or number, of the nanoparticles and microparticles have a diameter of less than five microns.

26. (previously presented) The formulation of claim 22 wherein 90%, by volume or number, of the nanoparticles and microparticles have a diameter of less than one micron.

27. (currently amended) The formulation of claim 22 wherein the taxane is present in a drug loading of up to 70% by weight of the nanoparticles.

28. (currently amended) The formulation of claim 22 wherein the taxane is present in a drug loading of between approximately 30 and 70% by weight of the nanoparticles.

29. (previously presented) The formulation of claim 22 further comprising a surfactant or excipient.

30-33. (cancelled)